

PATIENT INFORMATION LEAFLET

Citalopram 40 mg/ml Oral Drops, Solution

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Citalopram Oral Drops, Solution is and what it is used for
2. Before you take Citalopram Oral Drops, Solution
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1. What Citalopram Oral Drops, Solution is and what it is used for

The name of your medicine is Citalopram Oral Drops, Solution (called citalopram in the rest of this leaflet). This belongs to a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRI) antidepressants.

Everyone has a substance in their brain called serotonin. People who are depressed or anxious have lower levels of serotonin. These medicines help bring the levels back to normal.

Citalopram can be used to:

- Provide relief from the symptoms of depression or stop them coming back
- Provide relief from the symptoms of panic attacks.

2. Before you take Citalopram Oral Drops, Solution**Do not take Citalopram Oral Drops, Solution if:**

- you are allergic (hypersensitive) to citalopram or any other ingredients in this liquid (see section 6). An allergic reaction can include a rash, itching or shortness of breath
- you are taking a medicine called sumatriptan or pimozone
- you are taking MAOIs (Monoamine Oxidase Inhibitors) for depression such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide, selegiline (used for the treatment of Parkinson's disease)
- you are taking linezolid (an antibiotic)
- you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- you take medicines for heart rhythm problems or that may affect the heart's rhythm.

See the section below on ‘Taking other medicines’.

Take special care with Citalopram Oral Drops, Solution

Before you take citalopram, tell your doctor if:

- you have diabetes
- you have epilepsy (fits)
- you are having electroconvulsive therapy (ECT) where a small electric current is passed through the brain
- you have ever been treated for mania (overactive behaviour such as hallucinations, great excitement, and difficulty in concentrating or staying still) or panic disorder
- you have ever had a problem with uncontrolled bleeding or bleeding from ulcers in the stomach or intestine
- you have liver or kidney problems
- you suffer or have suffered from heart problems or have recently had a heart attack
- you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- you are under the age of 18. Citalopram is not normally used for children and adolescents under 18 years. However, a doctor may prescribe it because he/she decides that this is in their best interest (see section 4 below ‘If the medicine is prescribed to a child or adolescent under the age of 18’)
- you have problems with your eyes, such as raised pressure (glaucoma)
- low blood levels of sodium
- symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of treatment. Tell your doctor immediately if you experience these symptoms.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

DO NOT TAKE CITALOPRAM if you take medicines for:

- heart rhythm problems or medicines that may affect the heart’s rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine)
- pimozide – used for schizophrenia
- tramadol and sumatriptan – used for migraines and to relieve pain
- MAOIs (Monoamine Oxidase Inhibitors) – for depression (such as selegiline, linezolid, phenelzine, isocarboxazid, tranylcypromine and moclobemide)
 - Wait 14 days after stopping an MAOI before you take citalopram.
 - If you have been taking moclobemide, you will only need to wait 1 day before taking citalopram.

- Wait 7 days after stopping citalopram treatment before you take an MAOI.

If you have any further questions about this you should speak to your doctor.

Tell your doctor if you are taking any of the following:

- natural medicines containing a substance called ‘St John’s Wort’ (also called *Hypericum perforatum*) – used for depression
- anti-coagulant medicines – for thinning the blood (such as warfarin)
- non-steroidal medicines – for pain and inflammation (such as ibuprofen or aspirin)
- medicines for epilepsy (such as carbamazepine or phenytoin)
- medicines for diabetes (such as insulin)
- lithium, oxitriptan, bupropion, imipramine, desipramine and tryptophan – used for depression
- metoprolol – used for migraine, some heart problems and high blood pressure. The effects of either drug could be increased, decreased or altered
- mefloquine – used to treat malaria
- neuroleptics – used to treat schizophrenia
- cimetidine – used to treat stomach ulcers.

Taking Citalopram Oral Drops, Solution with food and drink

It is sensible to avoid drinking alcohol whilst taking citalopram.

Pregnancy and breast-feeding

Talk to your doctor before taking the medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Citalopram has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Make sure your midwife and/or doctor know you are on Citalopram. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

You should also contact your doctor straight away if you see any of the following symptoms in your baby: stiff or loose muscles, jitteriness or being too hot or cold, fits, feeding difficulties, vomiting, low blood sugar, overactive reflexes, tremor, irritability, lethargy, constant crying, sleepiness or sleeping difficulties.

Driving and using machines

Citalopram does not usually affect you being able to drive. However, it is possible that your illness or this medicine may affect your general attention and ability to concentrate. Do not drive or use machines if you are affected.

Important information about some of the ingredients of Citalopram Oral Drops, Solution

This medicine contains:

- Small amounts of alcohol (ethanol), less than 100mg per ml.
- Propyl parahydroxybenzoate and methyl parahydroxybenzoate. These may cause an allergic reaction (the allergy may happen some time after starting this medicine).

3. How to take Citalopram Oral Drops, Solution

Always take Citalopram Oral Drops, Solution exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- This medicine contains 40mg of citalopram in each 1ml.
- Take this medicine by mouth.
- Take once a day, either in the morning or evening.
- Count the required number of drops into your drink of water. Stir it briefly and then drink all of it.
- Your doctor will tell you how many citalopram drops to use. This depends on your illness.

It may take several days before you start to feel the medicine working. This is normal for this type of medicine.

Adults**Depression**

- The usual dose of citalopram is 16mg (8 drops)/(0.4ml) each day.
- This may be increased by your doctor to a maximum of 32mg (16 drops)/(0.8ml) each day.
- Treatment for depression usually lasts for at least 6 months.

Panic Disorder

- The starting dose of citalopram is 8mg (4 drops)/(0.2ml) each day for the first week before increasing the dose to 16 - 24mg (8 - 12 drops)/(0.4 - 0.6ml) each day.
- This may be increased by your doctor to a maximum of 32mg (16 drops)/(0.8ml) each day.
- Treatment for panic disorder usually lasts for at least 3 months.

Elderly Patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 8 - 16mg each day. Elderly patients should not usually receive more than 16mg (8 drops)/(0.4ml) each day.

Patients with special risks

If you have a liver problem, you should not receive more than 16mg (8 drops)/(0.4ml) each day.

Children and adolescents under the age of 18

Citalopram is not usually given to children and adolescents under the age of 18 (see Section 4 ‘If the medicine is prescribed to a child or adolescent under the age of 18’).

If you have previously taken Citalopram tablets, you will find that the dose of your medicine in mg given as drops is a bit lower than that of tablets. This is because your body more easily absorbs the drops than the tablets, so you need a lower dose to have the same effect.

The doses correspond as follows:

Tablets	Drops
10 mg	8 mg (4 drops)
20 mg	16 mg (8 drops)
30 mg	24 mg (12 drops)
40 mg	32mg (16 drops)

If you take more Citalopram Oral Drops, Solution than you should

Talk to a doctor or go to a hospital straight away. Some of the signs of overdose could be life-threatening. Signs of an overdose include: feeling sleepy or falling into a coma, fits or shaking (tremor), heart problems such as fast, slow or irregular heartbeats, changes in heart rhythm, sweating, feeling sick (nausea) or being sick (vomiting), breathing too quickly and deeply (hyperventilation), feeling dizzy or drowsy or running a high temperature (fever), changes in your blood pressure, unconsciousness, enlarged pupils, agitation, bluish skin, serotonin syndrome (see section 4).

If you forget to take Citalopram Oral Drops, Solution

Do not take a double dose to make up for the forgotten dose. Take your next dose as soon as you remember. Then go on as before.

If you stop taking Citalopram Oral Drops, Solution

Do not stop taking citalopram suddenly, even if you feel better. The doctor should reduce your dose gradually. This is because stopping too soon can lead to problems such as:

- feeling dizzy, confused or disorientated, feeling sick (nausea), being sick (vomiting) or problems with your eyesight
- tingling (like “pins and needles”), burning sensation and (less commonly) electric shock sensations
- headache, feeling stressed (anxious), sweating, having trouble sleeping with bad dreams
- your body shaking (tremor), fluttering or pounding heart
- diarrhoea
- feeling restless, agitated, emotional or irritable.

These usually last a few days. If this happens, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

After taking your medicine – special information on thoughts of suicide or worsening of your depression or anxiety.

Contact your doctor straight away if you have thoughts about harming yourself.

In the first few weeks of treatment with citalopram, thoughts of suicide or self-harm can happen. These symptoms may continue or worsen before you start to feel the full anti-depressant effect of the medicine.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have any distressing thoughts or experiences at any time during treatment, tell your doctor straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

After taking your medicine – possible side effects

Like all medicines, citalopram can cause side effects, although not everybody gets them.

If you have an allergic reaction to citalopram see a doctor straight away.

An allergic reaction may include:

- any kind of skin rash, flaking skin, boils or sore lips and mouth
- sudden wheezing, fluttering or tightness of the chest or collapse.

If you get any of the following symptoms you should stop taking Citalopram Oral Drops, Solution and see your doctor immediately:

- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Contact your doctor if you have any of the following serious side effects

- low levels of sodium in the blood (hyponatremia), signs of this include tiredness, confusion and twitching of your muscles
- low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms.

If this medicine is prescribed for a child or adolescent under the age of 18

Patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts, aggression, difficult behaviour.

If you get any of the following side effects, stop taking citalopram and see your doctor as soon as possible:

Common (affects less than 1 in 10 people)

- shaking (tremor)

- severe headache (migraine)
- pins and needles
- very fast and uneven heartbeats (palpitations)
- being sick (vomiting) or stomach pain
- itching of the skin and skin rash.

Uncommon (affects less than 1 in 100 people)

- feeling faint or light headed when standing up - this may be due to low blood pressure
- fast heart beats (tachycardia) or slower heart beats (bradycardia)
- difficulty passing water (urine), unable to control passing water or feeling thirsty with an increased need to pass water.

Rare (affects less than 1 in 1000 people)

- fits
- difficulty moving.

The following side effects have also been reported

- blood in your vomit or your bowel motions (stools) become black or stained with blood. If this happens, talk to your doctor straight away.

Tell your doctor if you get any of these side effects:

Very common (affects more than 1 in 10 people)

- disturbed or difficulty sleeping, feeling sleepy or drowsy
- feeling sick (nausea)
- dry mouth
- headache
- increased sweating
- feeling weak, tired.

Common (affects less than 1 in 10 people)

- loss of appetite
- feeling agitated, nervous, anxious, confused or lack of emotion
- decreased sex drive (libido)
- unable to concentrate or forgetting things
- dizziness
- eye focusing problems
- ringing in the ears
- yawning all the time
- swelling and irritation inside the nose
- constipation, diarrhoea, indigestion or wind (flatulence)
- strange taste in the mouth or making more saliva than normal
- unable to get an erection (impotence), failure to ejaculate or lack of orgasm in females
- muscle or joint pain
- weight loss
- bad dreams.

Uncommon (affects less than 1 in 100 people)

- red or purple spots on the skin which do not change colour when pressure is applied
- feeling hungry
- feeling aggressive
- increased levels of self awareness, seeing or hearing things that are not there (hallucinations)
- feeling elated or over excited, which causes unusual behaviour
- fainting
- eyesight problems including large pupils (the dark centre of the eye), narrow angle glaucoma
- hair loss
- weight gain
- vaginal bleeding in women, especially between periods
- sensitivity to sunlight
- swelling of the arms and legs.

Rare (affects less than 1 in 1000 people)

- an increased feeling of well-being
- increased sexual drive (libido)
- taste disturbance
- bleeding
- coughing
- liver problems, including swelling of the liver (hepatitis)
- fever.

The following side effects have also been reported

- reduction in blood platelets, which increases risk of bleeding or bruising
- feeling of being unwell, confused, weak, feeling sick (nausea), loss of appetite, feeling irritable - you may have something called 'inappropriate ADH secretion'
- panic attack
- grinding of the teeth or clenching of the jaw
- feeling restless
- high temperature, shaking sweating, diarrhoea, feeling confused or agitated – you may have something called 'serotonin syndrome'
- nose bleed
- bruising, swelling of the face or throat
- painful, persistent erection
- unusual secretion of the breast milk
- unusual muscle movements or stiffness or involuntary movements of the muscles
- changes to the results of tests to show how your liver is working.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Citalopram Oral Drops, Solution

- Keep out of the reach and sight of children.
- There are no special storage conditions for this medicine.
- After opening use within 16 weeks.
- Do not use citalopram after the expiry date (month, year) which is stated on the bottle and outer carton. The expiry date refers to the last day of that month.
- If it is out of date or the bottle has been open for more than 16 weeks or you no longer need it, ask your pharmacist how to dispose of it.
- Do not use Citalopram Oral Drops, Solution if you notice anything wrong with the medicine. Talk to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Citalopram Oral Drops, Solution contains

The active substance is Citalopram (as hydrochloride).

- Each ml of solution contains 40mg of citalopram.
- Each drop contains 2mg of citalopram.
- There are 20 drops in each ml of solution.
- Each 15ml bottle contains 300 drops of solution.

The other ingredients are: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethanol (76.00 mg per ml), hydroxyethylcellulose and purified water.

What Citalopram Oral Drops, Solution looks like and contents of the pack

Colourless to slightly yellow liquid.

15ml bottle with dropper.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

Manufacturer: Atlantic Pharma- Produções Farmacêuticas S.A., Rua da Tapada Grande No.2, 2710-089 Sintra, Portugal.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland – Citalopram 40mg/ml Oral Drops, solution.

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